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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,395	06/24/2005	David Chow	187035/US/3	9017
25763 7590 11/10/2009 DORSEY & WHITNEY LLP INTELLECTUAL PROPERTY DEPARTMENT SUITE 1500 50 SOUTH SIXTH STREET MINNEAPOLIS, MN 55402-1498				
EXAMINER WOODALL, NICHOLAS W				
ART UNIT 3775		PAPER NUMBER		
MAIL DATE 11/10/2009		DELIVERY MODE PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/500,395

Applicant(s)

CHOW ET AL.

Examiner

Nicholas Woodall

Art Unit

3775

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 August 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-39 and 41-44 is/are pending in the application.
- 4a) Of the above claim(s) 2-21, 24-35, 37-39 and 41-44 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 22, 23, 36 and 41-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 June 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 04/03/2009
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 31st, 2009 has been entered.

Drawings

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the cylindrical body of the first portion being forced radially outwards as stated in claim 23 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering

of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3. Claim 23 is rejected under 35 U.S.C. 101 because it is drawn to non-statutory subject matter. In claim 23, lines 2-3, applicant positively recites part of a human, i.e. "...the first portion has an enlarged head abutting an outer surface of one of the bone fragments...". Thus claims 1-7 include a human within their scope and are non-statutory.

A claim directed to or including within its scope a human is not considered to be patentable subject matter under 35 U.S.C. 101. The grant of a limited, but exclusive property right in a human being is prohibited by the Constitution. In *re Wakefield*, 422 F.2d 897, 164 USPQ 636 (CCPA 1970).

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claim 23 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 23 states that the distal end of the cylindrical body of the first portion is forced radially outwards from its longitudinal axis. The examiner is unable to find support in the specification or the drawings as originally filed. Therefore, the examiner is treating the limitation as new matter.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1, 22, 41, and 43 are rejected under 35 U.S.C. 102(b) as being anticipated by Lehmann (U.S. Patent 0,681,028).

Lehmann discloses a device (see Figure 5) comprising a first portion (A) and a second portion (B). The first portion is capable of extending through multiple bone fragments and includes a cylindrical body (a) having a proximal end (A2) and a distal end opposite the proximal end defining a longitudinal axis, wherein the cylindrical body is curved along the longitudinal axis. The second portion includes a cylindrical body (b) having a proximal end and a distal end (B2) opposite the proximal end defining a longitudinal axis, wherein the cylindrical body is curved along the longitudinal axis. The

second portion is slidably disposed substantially through, i.e. more than 50%, the first body and detachably coupled within the first portion to a locked position such that the distal end of the first portion abuts the distal end of the second portion, wherein the device is capable of stabilizing the multiple bone fragments.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims, 36, 42, and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kammerer (U.S. Publication 2001/0010005) in view of Lehmann (U.S. Patent 0,681,028).

Kammerer discloses a fastener, for example Figures 1-1A, comprising an elastic cylindrical body (32) curved along a longitudinal axis and enlarged portions (40) to hold multiple bone fragments (page 5 paragraph 075), wherein the portions of the device are elastically displaced, i.e. stretched and unstretched, to provide the forces to hold the separate tissue fragments. Kammerer further discloses a method of stabilizing a plurality of tissue, such as bone, comprising the steps of displacing a distal end of a first portion of the device through at least one tissue, i.e. a bone fragment, displacing the first portion of the device with a second portion of the device, i.e. release the elastically stretched device, to a locked position stabilizing the tissues, i.e. bone fragments. Kammerer fails to disclose the device having a first portion and a second portion sliding

interlocked relative to one another, wherein the second portions extends at least 50% of the way through the first portion. Lehmann teaches a fastener comprising a first portion (A) and a second portion (B) for the stabilization of a plurality of elements, wherein the second portion is displaced, i.e. slid within the first portion to a locked position, to provide the forced to hold the plurality of elements. The first portion includes a cylindrical body (a) having a proximal end (A2) and a distal end opposite the proximal end defining a longitudinal axis, wherein the cylindrical body is curved along the longitudinal axis. The second portion includes a cylindrical body (b) having a proximal end and a distal end (B2) opposite the proximal end defining a longitudinal axis, wherein the cylindrical body is curved along the longitudinal axis. The second portion is disposed substantially through, i.e. more than 50%, the first body and detachably coupled within the first portion to a locked position such that the distal end of the first portion abuts the distal end of the second portion. It would have been obvious to one having ordinary skill in the art to provide the fastener of Kammerer with the interlocked body portions as taught by the Lehmann reference to provide the forces to stabilize a plurality of elements. Using the known technique of a fastener having interlocking bodies to stabilize a plurality of elements to provide the forces for holding multiple bone tissues would have been obvious to one of ordinary skill in the art.

The device of Kammerer as modified by Lehmann discloses a method of stabilizing a plurality of bone fragments using the device as discussed above comprising the step of displacing a distal end of a first portion of the device through a bone fragment, displacing a second portion of the device through and within the first portion

until the distal end abuts the distal end of the first portion to lock the portions relative to one another and hold the bone fragments between the enlarged end portions of the first and second portions of the device.

Response to Arguments

10. Applicant's arguments with respect to claims 1, 22, 36, and 41-44 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO-892 for cited references the examiner felt were relevant to the application.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nicholas Woodall whose telephone number is (571)272-5204. The examiner can normally be reached on Monday to Friday 8:00 to 5:30 EST..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas Barrett can be reached on 571-272-4746. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nicholas Woodall/
Examiner, Art Unit 3775

/Thomas C. Barrett/
Supervisory Patent Examiner, Art
Unit 3775